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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,276	04/15/2000	GLENN F. SPAULDING	010-US-002	9303

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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/550,276	SPAULDING, GLENN F.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 August 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 10, 11, 13-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 10, 11, 13-31, and 33-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 8/4/04 is acknowledged and has been entered. Claims 1 and 10-13 have been amended. Currently, claims 1-4, 10, 11, 13-31, and 33-34 are pending and are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, line 3 is vague and indefinite in reciting, "a bar code label adapted to be interrogated" because it is unclear how the barcode has been modified, i.e. adapted, so as to be able to be interrogated. If Applicant intends that there is no adaptation or modification made to the barcode label so as to be differentially interrogated in comparison to other barcode labels, then Applicant should recite, "a barcode label that is interrogated".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to a cytometer having a rotating means that rotates a transparent cylinder, a light source that illuminates the transparent cylinder while it rotates, a detector that detects light signal from the transparent cylinder while it rotates, a determining means that determines at least one cytometric characteristic of the sample disposed in the sample, and a movement means for moving the transparent cylinder, the light source, and the detector in a longitudinal axis relative to one another. "Cytometric characteristics" as recited in the claims encompasses a broad scope which includes information that is incorporated into a barcode label. In the hospital setting, barcode labels are used in identifying blood collected from patients and include information such as patient's name, social security number, age, blood type, i.e. B positive which describes a presence of B and Rh antigens in the blood cells of the patient, and diagnosis, i.e. acute myelocytic leukemia, which provides information that a patient's white blood cell count is high and have cytometric characteristics that includes large granular young myelocytic and blast cells, or sickle cell anemia which provides information that some of patient's red blood cells are characteristically sickled or S-shaped. Accordingly,

3. Claims 1, 2, 10, 11, 21, 22, 33, and 34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nishina et al. (US Patent 5,582,795) for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 24, 25, and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Milch (US Patent 5,352,879) for reasons of record.
5. Claim 29 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Izumi (US Patent 5,126,554) for reasons of record.

6. Claims 3, 13-18, 26-28, and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834) for reasons of record.

7. Claims 4, 19, 20, and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834) as applied to claims 13-18, 26-28, and 31 above, and further in view of Surmodics, Inc. for reasons of record.

Response to Arguments

8. Applicant's arguments filed 8/4/04 have been fully considered but they are not persuasive.

A) Applicant argues that Nishina does not anticipate claims 1 and 10 because it does not teach "determining at least one cytometric characteristic of a sample disposed in said transparent cylinder". Applicant specifically submits that determining a cytometric characteristic from the sample inside the container is so different an operation from reading a bar code affixed to the container, that Nishina cannot be said to even suggest the claimed action.

In response, it is noted that "*from a sample inside a rotating container*" is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, Nishina reads on the claimed invention because claims 1 and 10 do not appear to delimit the recited cytometric characteristics determined, to those that are obtained directly from the sample at the time of the detection process. As recited, the claims still read on determining cytometric characteristics encompassing information incorporated into a barcode label, of the sample disposed inside the rotating cylinder such as for example patient's name, blood type, diagnosis, i.e. acute myelocytic leukemia, which provides information that white blood cells are large, granular, and have enlarged nucleus, or sickle cell anemia which provides information that some of patient's red blood cells are characteristically sickled or S-shaped. Moreover, Applicant's argument that Nishina cannot be said to even suggest the claimed action is not persuasive because the claims

are drawn to an apparatus, not a process, and Applicant does not recite a determining means that is structurally distinct from that taught by Nishina so as to be able to manipulatively perform a distinct determining process. Accordingly, the rejection of claims 1, 2, 10, 11, 21, 22, 33, and 34 under 35 U.S.C. 102(b) as being anticipated by Nishina et al. (US Patent 5,582,795) is being maintained.

B) Applicant argues that the combination of Nishina with Milch does not render claims 24, 25, and 30 obvious, the combination of Nishina with Izumi does not render claim 29 obvious, the combination of Nishina and Anderson does not render claims 3, 13-18, 26-28, and 31 obvious, and the combination of Nishina, Anderson, and Surmodics, Inc. does not render claims 4, 19, 20, and 23 obvious. Applicant specifically contends that the 103 rejections aforementioned fall since the Nishina reference used in the 102 rejection does not anticipate the claimed invention because it does not teach "determining at least one cytometric characteristic of a sample disposed in said transparent cylinder" which is so different an operation from reading a bar code affixed to the container, that Nishina cannot be said to even suggest the claimed action.

In response, Nishina reads on the claimed invention because claims 1 and 10 do not appear to delimit the recited cytometric characteristics determined, to those that are obtained directly from the sample at the time of the detection process. As recited, the claims still read on determining cytometric characteristics encompassing information incorporated into a barcode label, of the sample disposed inside the rotating cylinder such as for example patient's name, blood type, diagnosis, i.e. acute myelocytic

leukemia, which provides information that white blood cells are large, granular, and have enlarged nucleus, or sickle cell anemia which provides information that some of patient's red blood cells are characteristically sickled or S-shaped. Further, the rejected claims are drawn to an apparatus, not a process, which does not recite a determining means that is structurally distinct from that taught by Nishina so as to be able to manipulatively perform a distinct determining process. Accordingly, all the obviousness rejections in this Office Action and the Office Action filed 5/6/2004 based on Nishina et al. as primary reference are being maintained.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
October 14, 2004

(rg)

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
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